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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,401	05/12/2005	Filip Arnaut	VANM199.005APC	6305

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EXAMINER

BADR, HAMID R

ART UNIT	PAPER NUMBER
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1794

NOTIFICATION DATE	DELIVERY MODE
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09/17/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/510,401	Applicant(s) ARNAUT ET AL.	
	Examiner HAMID R. BADR	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 23-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 23-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' amendment filed on 3/17/2008 is acknowledged. All outstanding rejections of record are overcome by applicant's amendment and arguments. New grounds of rejection are set forth below.

Claims 1-18 and 23-31 are being considered on the merits.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the microorganism(s) is/are essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism(s) is/are not so obtainable or available, the requirements of 35 USC 112 may be satisfied by deposit(s) of the microorganism(s). The specification does not disclose a repeatable process to obtain the microorganism(s) and it is not clear from the specification or record that the microorganism(s) is/are readily available to the public.

This rejection may be overcome by establishing that the each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein.

If the depository is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his/her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney over his/her registration number, showing that,

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and,
- (d) the deposit will be replaced if it should ever become inviable.

The specification must also state the date of deposit(s), the number(s) granted the deposit(s) by the depository and the name and address of the depository.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 is indefinite for “a sufficiently effective amount”. It is not clear what is meant by “a sufficiently effective amount”. It is unclear what the applicants regard as the invention.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

6. Claims 1, 6-7, 9-10, 13-16, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Klingenberg et al. (DD 156,714 A; hereinafter R1).

7. R1 teaches preparing a heat stable thermitase from *Thermoactinomyces vulgaris*. This enzyme is a proteinase for weakening gluten in the preparation of wafers, other cereal and bakery products (Page 1, paragraph 1 and Claim 1).

Art Unit: 1794

8. Although there is no explicit disclosure of preventing or retarding staling during the baking process of the bakery products, given that R1 discloses method and improver identical to that presently claimed, it is clear that the method and the improver would inherently prevent or retard staling during the baking process of the bakery products.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 3-4, 8, 12, 17, 25, 27, and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klingenberg et al. (DD 156,714 A; hereinafter R1) in view of Olesen et al. (US 6,110,508; hereinafter R2)

11. R1 teaches preparing a heat stable thermitase from *Thermoactinomyces vulgaris*. This enzyme is a proteinase for weakening gluten in the preparation of wafers, other cereal and bakery products (Page 1, paragraph 1 and Claim 1).

12. Regarding claim 3, it is obvious that a thermostable enzyme with a high optimum temperature for activity will be much more active than the same enzyme at much lower temperature e.g. 25C. The property of a much higher activity of a thermostable enzyme at higher temperature compared to the activity of the same enzyme at lower temperature will be inherent in the enzyme.

Art Unit: 1794

R1 is silent regarding addition of other enzymes and emulsifier to the dough.

13. R2 discloses the use of lipase together with other enzymes such as cellulase, hemicellulase, xylanase, glucose oxidase, peroxidase, amyloglucosidase, and alpha-amylase in bakery products including bread (Col. 5, lines 33-46). Bacterial alpha-amylase is known in the art and is a thermostable enzyme. It would be obvious to those of skill in the art to select a thermostable amylase such as a bacterial amylase to add to the dough formulations.

20. R2 teaches using emulsifiers such as mono and diglycerides, diacetyl tartaric acid esters of mono- and diglycerides (DATEM), sugar esters of fatty acids, lactic acid esters of monoglycerides, polyoxyethylene stearates, phospholipids and lecithin in their dough improver (Col. 6, lines 46-56). These emulsifiers are used to improve dough extensibility as well as the consistency and storage stability of the bread.

21. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use a thermostable protease as taught by R1 and include the improving enzymes and emulsifiers taught by R2 to receive the benefits of the dough improving properties of such enzymes and emulsifiers to prevent or retard staling in baked goods. Absent any evidence to contrary and based on the combined teachings of the cited references, there would have been a reasonable expectation of success.

Art Unit: 1794

14. Claims 7 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over R1 in view of Terada et al. (US 5,124,261; hereinafter R3) and Chernoglazov et al. (RU 2,177,799; hereinafter R4).

15. R1 teaches preparing a heat stable thermitase from *Thermoactinomyces vulgaris* as described above. R1 is silent regarding protease of *Thermus aquaticus* and Keratinase of *Bacillus lecheniformis*.

16. R3 discloses a process for the production of aqualysin I employing a genetic engineering procedure by cultivation of *Thermus qauaticus* (Col. 1, lines 34-52 and Col. 8, lines 31-51).

17. R3 is silent regarding a keratinase enzyme.

18. R4 discloses a new keratinase from *Bacillus licheniformis*. The keratinase can be used in the food industry (Abstract).

16. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the teachings of R1 by including the protease and keratinase taught by R3 and R4. One would do so to receive the benefits of a thermostable protease and keratinase at least at the early stages of baking where the temperature is high enough for the activation of these thermostable enzymes and yet not that high to denature such enzymes.. Absent any evidence to contrary and based on the combined teachings of the cited references, there would have been a reasonable expectation of success.

Art Unit: 1794

19. Claims 2, 5, 11, 23, 24, 26, and 28-29 rejected under 35 U.S.C. 103(a) as being unpatentable over R1 as applied above, further in view of Stetter (US 5,714,373; hereinafter R5).

20. R1 teaches preparing a heat stable thermitase from *Thermoactinomyces vulgaris* as described above.

21. R5 discloses the isolation and identification of a thermostable protease from *Thermococcus* which has an optimum temperature range between 60C and 90C (col.7, lines 38-41).

22. It would have been obvious to one of ordinary skill in the art to use proteases which have an optimum range of activity in the 60C-90C.

23. Claims 5 and 26 are obvious due to the fact that serine proteases have a serine residue at the active site which acts as a nucleophilic residue in proteolytic activities, being active at neutral or alkaline pH.

24. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to employ the thermostable proteases from various sources as taught by R1, R3, R4 and use them at optimally at 60-90C as taught by R5.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-T 5:00 to 3:30 (Friday off).

Art Unit: 1794

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr
Examiner
Art Unit 1794

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1794